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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,128	09/20/2006	Kimihiro Mabuchi	19461-005US1 548062	4588
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EXAMINER MENON, KRISHNAN S				
ART UNIT 1797		PAPER NUMBER		
NOTIFICATION DATE 07/15/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/599,128

Applicant(s)

MABUCHI ET AL.

Examiner

Krishnan S. Menon

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 12-15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-8,10, 12-15 and 17-21 are pending as amended 7/1/10 in the RCE of 9/22/09.

Claims 17-21 are withdrawn.

Effective date – 3/22/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites conflicting ranges. Claim 10 depends from claim 1, which has the range 20-40%, which conflicts with the 5-20%. Claim 10 does not further limit claim 1.

Claim Rejections - 35 USC § 103

Claims 1-8,10 and 12-15 are rejected under 35 U.S.C. 103(a) as unpatentable over Shimagaki et al (US 6,103,117)

Claim interpretation: Applicant's claim 1 recite a perm-selective membrane made from polysulfone and polyvinyl pyrrolidone. The D/C ratio of PVP content in the non-blood contacting surface layer D and the blood contacting surface layer C is 1.1 or more, the blood-side PVP content 20-40%, and the non-blood side PVP content 25-

50%. The remaining limitations of claim 1 describe how the membrane performs with respect to bovine blood, in terms of albumin sieving coefficient over certain time periods when the membrane is operated with certain fluxes.

Shimagaki teaches hollow fiber membranes made from polysulfone and PVP – see examples, with about 40 microns thickness, about 33% PVP content. This reference does not explicitly state the sieving coefficient or albumin clearance, but teaches albumin permeabilities of about 1.2% or less (examples, abstract).

Membrane is asymmetric, which means it has a thin skin layer inherently the range claimed.

The membrane properties of albumin sieving coefficient, etc., would be inherent, because the membrane is made of the same material, and has the same or similar structure. More over, the membrane is made for the same application as that of the applicant's.

Cross-linked – see column 11, starting at line 42.

Fiber diameter and thickness – see about 40 microns in example 7. The fiber is spun from a 0.3mm OD/0.2mm ID nozzle in all examples – therefore, the fiber thickness would be within the range claimed.

Aperture ratio: this is also an inherent characteristic of the membrane from the way it is made, and since the applicant's membrane is made the same way as that of the reference, it is inherent in the reference.

Regarding the polyvinyl pyrrolidone content of the blood-contacting and non-blood—contacting surfaces(the D/C ratio), applicant's disclosure (pre-grant publication,

paragraph 0147-0148) describes the orientation of PVP as related to the spinning nozzle dimensions, as well as the molecular weight of the PVP (paragraph 0082), and the composition of the internal liquid (paragraph 0060). The reference teaches spinning nozzle dimensions and molecular weights within this range and the inner solution of the same composition, and therefore, this characteristic are also inherent in the membrane of the reference. Similarly, since the compositions and the method of making is the same, the mechanical strength of the membrane also would be in the same range as claimed. The declaration presented show some evidence that this ratio in the reference is in the range 0.9-1.0. However, this ratio appears to have no criticality and applicant has failed to show any criticality to this ratio. Therefore, the reference membrane is deemed as an obvious equivalent to the claimed membrane.

Specifically, see the teaching in column 6, lines 49-67.

The Mabuchi Declaration filed 7/1/10:

Applicant's declaration filed 7/1/10 does not provide a persuasive evidence for patentability over the cited prior art.

According to the declaration and the test results of Table 2, the D/C ratio ranges from 0.9-1.0, and does not meet the claimed range of 1.1 or greater. This is the only condition that is alleged as not being met by the reference membrane.

However, it is respectfully submitted that this element does not appear to be critical to the performance of a dialysis membrane. The critical parameters are identified as the albumin sieving coefficient being in the range 0.005-0.04, very low albumin sieving

coefficient being important to retain albumin, while the membrane is capable of removing the lower molecular weight toxic substances, effectiveness of which being identified by the clearance of α -1 microglobulin, which should be greater than 15 ml/min/m² (paragraph 0048-0051 of application publication). The declaration fails to show any criticality for the D/C ratio to be 1.1 or more. The actual concentration of PVP on the surfaces appears to be more critical to α -1 microglobulin and hydrophilicity than the ratio (paragraph 0058; 0067 and 0076).

Response to Arguments

Applicant's arguments filed 7/1/10 have been fully considered but they are not persuasive. They are addressed above.

The Examiner wishes to point out that the definition of the % PVP content on the inner and outer surfaces of the membrane is unclear. It is suggested that applicant provide clarification about the definition of this %PVP content, that is, whether it is the ratio of PVP/polysulfone, or PVP to total mass of polymer, $\text{PVP}/(\text{PVP}+\text{polysulfone})$.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797